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(Original Signature of Member)

109TH CONGRESS
2D SESSION

H. R. _____

To amend titles XVIII and XIX of the Social Security Act to to assure uninterrupted access to necessary medicines under the Medicare prescription drug program.

IN THE HOUSE OF REPRESENTATIVES

Mr. DINGELL introduced the following bill; which was referred to the Committee on _____

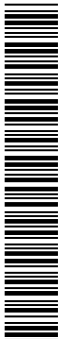
A BILL

To amend titles XVIII and XIX of the Social Security Act to to assure uninterrupted access to necessary medicines under the Medicare prescription drug program.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Medicare Prescription Drug Emergency Guarantee Act
6 of 2006”.



1 (b) TABLE OF CONTENTS.—The table of contents of
2 this Act is as follows:

- Sec. 1. Short title; table of contents.
- Sec. 2. Protections to provide for uninterrupted access to medicines.
- Sec. 3. Required application of intermediate sanctions to protect against fraud and abuse.
- Sec. 4. Changes of enrollment in prescription drug plans and MA–PD plans allowed twice during year.
- Sec. 5. Prohibiting additional restrictions or limitations on coverage during year.
- Sec. 6. MedPAC study on appropriate enrollment of dual eligible individuals.
- Sec. 7. Prohibition on conditioning Medicaid eligibility on enrollment in Medicare part D coverage or other creditable coverage.
- Sec. 8. Reimbursement of third parties for 2006 transition costs.

3 **SEC. 2. PROTECTIONS TO PROVIDE FOR UNINTERRUPTED**
4 **ACCESS TO MEDICINES.**

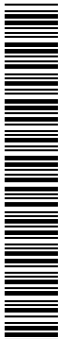
5 (a) MINIMUM STANDARD TRANSITION COVERAGE.—

6 (1) IN GENERAL.—Section 1860D–4(b) of the
7 Social Security Act (42 U.S.C. 1395w–104(b)) is
8 amended by adding at the end the following new
9 paragraph:

10 “(4) UNINTERRUPTED ACCESS TO MEDI-
11 CINES.—

12 “(A) MINIMUM STANDARD TRANSITION
13 COVERAGE.—A PDP sponsor offering a pre-
14 scription drug plan under this part or an MA–
15 PD plan under part C shall provide minimum
16 standard transition coverage in accordance with
17 subparagraph (B).

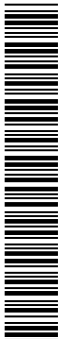
18 “(B) REQUIREMENTS.—The minimum
19 standard transition coverage under this sub-
20 paragraph, with respect to a part D eligible in-



1 dividual who is enrolled in a prescription drug
2 plan (or an individual who is presumed to be
3 such an individual pursuant to subparagraph
4 (F)) who presents a prescription for a drug at
5 a pharmacy, is the following:

6 “(i) GUARANTEED INITIAL SUPPLY,
7 REGARDLESS OF COVERAGE LIMITATIONS
8 OR RESTRICTIONS.—In the case that the
9 PDP sponsor of such plan uses a for-
10 mulary that does not cover the drug or
11 otherwise imposes a restriction on the cov-
12 erage of the drug (such as through the ap-
13 plication of a preferred status, usage re-
14 striction, step therapy, prior authorization
15 or a quantity limits) and during the period
16 in which such individual has been enrolled
17 in such plan the individual has not pre-
18 viously sought coverage under the plan for
19 such drug the plan shall provide for the
20 following:

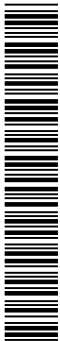
21 “(I) MINIMUM SUPPLY OF PRE-
22 SCRIPTION DRUG.—The plan must
23 provide for coverage for at least a 60-
24 day supply (or a 90-day supply in the
25 case of an individual who is a resident



1 of a long-term care facility) of the
2 drug, or, if less, a supply of the drug
3 that is the full amount of the pre-
4 scription.

5 “(II) INFORMATION ON FOR-
6 MULARY, PRESCRIPTION DRUG PLANS,
7 AND APPEAL RIGHTS.—The plan must
8 provide the individual with a standard
9 notice developed by the Secretary that
10 informs the individual about the limi-
11 tations and restrictions of the cov-
12 erage of the drug, that describes the
13 rights of the individual with respect to
14 requesting a determination under sub-
15 section (g)(2) or an appeal of such a
16 determination under subsection (h),
17 that describes any ability of the indi-
18 vidual to change the election of such
19 plan under section 1860D–1(b)(1)(B),
20 and that informs the individual about
21 sources of information on prescription
22 drug plans to make such a change in
23 plans.

24 “(III) REFILLS DURING PENDING
25 APPEAL.—In the case of such an indi-

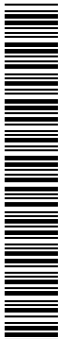


1 vidual who brings an appeal under
2 subsection (h), with respect to the
3 prescription drug involved, an addi-
4 tional supply of the drug (for the
5 amount of days provided to the indi-
6 vidual under subclause (I)) during the
7 period ending on the date on which a
8 final determination is made on the ap-
9 peal.

10 “(ii) GUARANTEED SUPPLY WHEN UN-
11 ABLE TO VERIFY PLAN ENROLLMENT.—In
12 the case that the pharmacy is unable to lo-
13 cate or verify the individual’s enrollment in
14 such plan through a reasonable effort:

15 “(I) MINIMUM SUPPLY OF PRE-
16 SCRIPTION DRUG.—The plan must
17 provide for coverage for at least a 60-
18 day supply (or a 90-day supply in the
19 case of an individual who is a resident
20 of a long-term care facility) of the
21 drug, or, if less, a supply of the drug
22 that is the full amount of the pre-
23 scription.

24 “(II) REFILLS.—The plan must
25 provide an additional 60-day supply

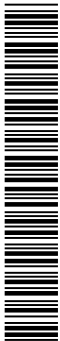


1 (or a 90-day supply in the case of an
2 individual who is a resident of a long-
3 term care facility) of the drug, or if
4 less, a supply of the drug that is the
5 full amount of the prescription, if the
6 pharmacy continues to be unable to
7 locate the individual's enrollment
8 through such reasonable efforts when
9 a prescription is presented on or after
10 the date that a prescription refill is
11 appropriate.

12 “(C) REIMBURSEMENTS.—

13 “(i) REIMBURSEMENTS TO PHAR-
14 MACIES.—

15 “(I) IN GENERAL.—If a phar-
16 macy provides prescription drugs for
17 which the minimum standard transi-
18 tion coverage is required under sub-
19 paragraph (B), the Secretary shall re-
20 imburse the pharmacy for the costs
21 incurred in providing the prescription
22 drugs, including acquisition costs, dis-
23 pensing costs, and other overhead
24 costs. The Secretary shall provide
25 prompt payment (consistent with the



1 provisions of section 1842(c)(2)) of
2 such reimbursements from the Medi-
3 care Prescription Drug Account under
4 section 1860D-16 of the Social Secu-
5 rity Act (42 U.S.C. 1395w-116).
6 Such reimbursements shall be deemed
7 to be payments from such Account
8 under subsection (b) of such section.

9 “(II) SANCTIONS FOR FRAUDU-
10 LENT CLAIMS.—In the case of a phar-
11 macy that knowingly provides to the
12 Secretary false information in connec-
13 tion with a claim for reimbursement
14 under subclause (I), the Secretary
15 may impose a civil money penalty in
16 an amount not to exceed \$10,000 for
17 each such claim. The provisions of
18 section 1128A (other than subsections
19 (a) and (b) and the second sentence of
20 subsection (f)) shall apply to a civil
21 money penalty under the previous sen-
22 tence in the same manner as such
23 provisions apply to a penalty or pro-
24 ceeding under section 1128A(a).



1 “(ii) RECOVERY FROM PLANS OF
2 PHARMACY REIMBURSEMENTS.—The Sec-
3 retary shall establish a process for recov-
4 ering the reimbursements made to phar-
5 macies under clause (i) from prescription
6 drug plans and MA–PD plans if the Sec-
7 retary determines that such plans should
8 have incurred such costs. Amounts recov-
9 ered pursuant to the preceding sentence
10 shall be deposited in the Medicare Pre-
11 scription Drug Account.

12 “(iii) APPLICATION OF INTERMEDIATE
13 SANCTIONS.—In the case of a failure of a
14 prescription drug plan under this part or
15 an MA–PD plan under part C to provide
16 for the minimum coverage required under
17 subparagraph (B), the failure shall be
18 treated as a failure to provide medically
19 necessary items and services under section
20 1857(g)(1)(A), as applied by section
21 1860D–12(b)(3)(E), and the Secretary
22 shall impose intermediate sanctions under
23 such section 1857(g).

24 “(D) COST-SHARING.—The cost-sharing
25 for a prescription filled pursuant to subpara-



1 graph (B) for an individual shall be in accord-
2 ance with the prescription drug plan in which
3 the individual attests to be enrolled and the
4 class of individual (such as subsidy-eligible indi-
5 viduals) to which the individual so attests.

6 “(E) REFUNDS TO INDIVIDUALS WITH IN-
7 APPROPRIATE CHARGES.—If the Secretary de-
8 termines, in accordance with a method deter-
9 mined by the Secretary, that an individual was
10 inappropriately charged for a prescription drug
11 dispensed to such individual under this part or
12 part C, the Secretary shall—

13 “(i) reduce payments to the sponsor
14 of the prescription drug plan under section
15 1860D–15 or to the organization offering
16 the MA–PD plan under section 1853 that
17 inappropriately charged the individual by
18 an amount equal to the amount the indi-
19 vidual was inappropriately charged; and

20 “(ii) refund such amount to the indi-
21 vidual within 30 days of the date of the de-
22 termination that the individual was inap-
23 propriately charged.

24 “(F) PRESUMPTIVE ELIGIBILITY.—

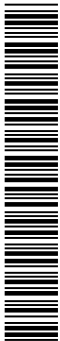


1 “(i) SUBSIDY-ELIGIBLE INDIVID-
2 UALS.—For purposes of this paragraph, an
3 individual shall be presumed to be a dual
4 eligible individual or subsidy-eligible indi-
5 vidual if the individual self attests to being
6 such an individual, respectively.

7 “(ii) PLAN ENROLLMENT.—For pur-
8 poses of this paragraph, an individual shall
9 be presumed to be enrolled in a prescrip-
10 tion drug plan under this part or an MA-
11 PD plan under part C if the individual self
12 attests to being enrolled under such plan.

13 “(iii) INDIVIDUAL LIABLE FOR COSTS
14 OF FALSE ATTESTATION.—

15 “(I) IN GENERAL.—If the Sec-
16 retary, as the result of verification ac-
17 tivities conducted by the Secretary,
18 determines after a fair hearing that
19 an individual has knowingly made a
20 false self-attestation described in
21 clause (i) or (ii) or in subparagraph
22 (D), the Secretary may, subject to
23 subclause (II), seek recovery from the
24 individual for the full amount of the
25 cost of benefits provided to the indi-



1 vidual under this paragraph as a re-
2 sult of such self attestation.

3 “(II) EXCEPTION.—The Sec-
4 retary shall at its discretion not seek
5 recovery under subclause (I) if the
6 Secretary determines that it would not
7 be cost-effective to do so.

8 “(III) REIMBURSEMENTS TO
9 FEDERAL GOVERNMENT.—Any
10 amounts recovered by the Secretary in
11 accordance with this clause shall be
12 returned to the prescription drug plan
13 or MA–PD plan if the Secretary has
14 previously recovered payment from
15 such plan.

16 “(iv) REQUIREMENTS FOR SELF AT-
17 TESTATION.—The Secretary shall promul-
18 gate requirements for self attestations
19 under this subparagraph, but the failure of
20 the Secretary to promulgate such require-
21 ments shall not preclude the applications
22 of the previous provisions of this subpara-
23 graph.”.

24 (2) EFFECTIVE DATE.—The amendment made
25 by paragraph (1) shall take effect on the date of the



1 enactment of this Act, but shall apply to prescription
2 drugs dispensed on and after January 1, 2006.

3 (b) NOTICE FOR CHANGE IN FORMULARY AND
4 OTHER RESTRICTIONS OR LIMITATIONS ON COVERAGE.—

5 (1) IN GENERAL.—Section 1860D–4(a) of such
6 Act (42 U.S.C. 1395w-104(a)) is amended by adding
7 at the end the following new paragraph:

8 “(5) ANNUAL NOTICE OF CHANGES IN FOR-
9 MULARY AND OTHER RESTRICTIONS OR LIMITATIONS
10 ON COVERAGE.—Each PDP sponsor offering a pre-
11 scription drug plan (and each MA organization of-
12 fering an MA–PD plan) shall furnish to each en-
13 rollee at the time of each annual coordinated election
14 period (referred to in section 1860D–1(b)(1)(B)(iii))
15 for a plan year a notice of any changes in the for-
16 mulary or other restrictions or limitations on cov-
17 erage of a covered part D drug under the plan that
18 will take effect for the plan year.”.

19 (2) EFFECTIVE DATE.—The amendment made
20 by paragraph (1) shall apply to annual coordinated
21 election periods beginning after the date of the en-
22 actment of this Act.

23 (c) STANDARDIZED FORMS AND PROCEDURES FOR
24 RECONSIDERATIONS AND APPEALS.—



1 (1) IN GENERAL.—Section 1860D–4 of such
2 Act (42 U.S.C. 1395w-104) is amended by adding at
3 the end the following new subsection:

4 “(1) STANDARDIZED FORMS AND PROCEDURES FOR
5 RECONSIDERATIONS AND APPEALS.—

6 “(1) STANDARD ENROLLEE NOTICE.—The Sec-
7 retary shall develop a standard notice to be distrib-
8 uted by a prescription drug plan (or an MA–PD
9 plan) to an enrollee when a covered part D drug pre-
10 scribed for the enrollee is not covered, or the cov-
11 erage of such drug is otherwise restricted, by the
12 plan.

13 “(2) STANDARDIZED PROCESS FOR RECONSID-
14 ERATIONS AND APPEALS.—The Secretary shall re-
15 quire prescription drug plans and MA–PD plans to
16 follow the same standardized process for reconsider-
17 ations and redeterminations under subsections (g)
18 and (h). Such process shall require that determina-
19 tions regarding medical necessity are based on pro-
20 fessional medical judgement, the medical condition
21 of the enrollee, the treating physician’s recommenda-
22 tion, and other medical evidence.”.

23 (2) EFFECTIVE DATE.—The Secretary of
24 Health and Human Services shall provide for the
25 standard notice and the standardized process, and



1 the application of such notice and process, under the
2 amendment made by paragraph (1) by not later
3 than January 1, 2007.

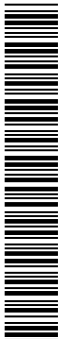
4 **SEC. 3. REQUIRED APPLICATION OF INTERMEDIATE SANC-**
5 **TIONS TO PROTECT AGAINST FRAUD AND**
6 **ABUSE.**

7 (a) IN GENERAL.—Section 1860D–12(b)(3)(E) of
8 the Social Security Act (42 U.S.C. 1395w–112(b)(3)(E))
9 is amended by inserting “and the reference to ‘may pro-
10 vide’ in section 1857(g)(1) is deemed a reference to ‘shall
11 provide’” after “this part”.

12 (b) APPLICATION TO MA–PD PLANS.—Section
13 1857(g)(1) of such Act (42 U.S.C. 1395w–27(g)(1)) is
14 amended by inserting “(or in the case of an MA–PD plan
15 or a prescription drug plan under part D, the Secretary
16 shall provide)” after “may provide”.

17 **SEC. 4. CHANGES OF ENROLLMENT IN PRESCRIPTION**
18 **DRUG PLANS AND MA–PD PLANS ALLOWED**
19 **TWICE DURING YEAR.**

20 (a) ADDITIONAL ELECTION PERMITTED ONCE EACH
21 YEAR OUTSIDE OF ANNUAL COORDINATED ELECTION
22 PERIOD.—Section 1851(e)(4) of the Social Security Act
23 (42 U.S.C. 1395w–21(e)(4)) is amended by inserting
24 “once every year, and in addition,” after “make a new
25 election under this section”.



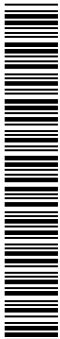
1 (b) EFFECTIVE DATE.—The amendment made by
2 subsection (a) shall take effect as of the date of the enact-
3 ment of this Act.

4 **SEC. 5. PROHIBITING ADDITIONAL RESTRICTIONS OR LIM-**
5 **TATIONS ON COVERAGE DURING YEAR.**

6 (a) IN GENERAL.—Section 1860D–4(b)(4) of the So-
7 cial Security Act (42 U.S.C. 1395w-104(b)(4)) is amended
8 by inserting after subparagraph (F) the following new
9 subparagraph:

10 “(G) PROHIBITING ADDITIONAL RESTRIC-
11 TIONS OR LIMITATIONS ON COVERAGE DURING
12 YEAR.—A prescription drug plan and an MA-
13 PD plan may only impose a restriction or limi-
14 tation on the coverage of a covered part D drug
15 (such as through the application of a formulary,
16 preferred status, usage restriction, step therapy,
17 prior authorization, or a quantity limitation)
18 only at the beginning of a plan year, except in
19 the case that the Commissioner of Food and
20 Drugs issues a clinical warning during a year
21 that imposes such a restriction or limitation on
22 the drug.”.

23 (b) EFFECTIVE DATE.—The amendment made by
24 subsection (a) shall take effect on the date of the enact-
25 ment of this Act and shall apply to the removal of a drug



1 or a change in the status of such drug on and after such
2 date.

3 **SEC. 6. MEDPAC STUDY ON APPROPRIATE ENROLLMENT**
4 **OF DUAL ELIGIBLE INDIVIDUALS.**

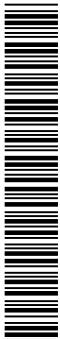
5 (a) STUDY.—The Medicare Payment Advisory Com-
6 mission shall conduct a study to determine the extent to
7 which full-benefit dual eligible individuals (as defined in
8 section 1935(c)(6) of the Social Security Act (42 U.S.C.
9 1396u5(c)(6)) were enrolled (by assignment or otherwise)
10 in the most appropriate prescription drug plans under
11 part D of title XVIII of such Act for such individuals.

12 (b) REPORT.—The Commission shall submit a report
13 to Congress on the study under subsection (a) not later
14 than February 1, 2007.

15 **SEC. 7. PROHIBITION ON CONDITIONING MEDICAID ELI-**
16 **BILITY ON ENROLLMENT IN MEDICARE PART**
17 **D COVERAGE OR OTHER CREDITABLE COV-**
18 **ERAGE.**

19 (a) IN GENERAL.—Section 1935 of the Social Secu-
20 rity Act (42 U.S.C. 1396v) is amended by adding at the
21 end the following new subsection:

22 “(f) PROHIBITION ON CONDITIONING MEDICAID ELI-
23 GIBILITY ON ENROLLMENT IN MEDICARE PART D COV-
24 ERAGE OR OTHER CREDITABLE COVERAGE.—



1 “(1) IN GENERAL.—A State shall not condition
2 eligibility for medical assistance under the State
3 plan for a part D eligible individual (as defined in
4 section 1860D–1(a)(3)(A)) who is enrolled in cred-
5 itable prescription drug coverage described in any of
6 subparagraphs (C) through (H) of section 1860D–
7 13(b)(4) on the individual’s enrollment in a prescrip-
8 tion drug plan under part D of title XVIII or an
9 MA–PD plan under part C of such title.

10 “(2) COORDINATION OF BENEFITS WITH PART
11 D FOR OTHER INDIVIDUALS.—Nothing in this sub-
12 section shall be construed as prohibiting a State
13 from coordinating medical assistance under the
14 State plan with benefits under part D of title XVIII
15 for individuals not described in paragraph (1).”.

16 (b) TREATMENT OF STATE PLAN AMENDMENTS, RE-
17 DETERMINATION OF ELIGIBILITY.—In the case of a State
18 that, as of the date of the enactment of this Act, has an
19 approved amendment to its State plan under title XIX of
20 the Social Security Act with a provision that conflicts with
21 section 1935(f) of such Act (as added by subsection (a)),
22 such provision is, as of such date of enactment, null and
23 void. The State shall redetermine any applications for
24 medical assistance that have been denied solely on the
25 basis of such a State plan amendment not later than De-



1 cember 31, 2006. Such redetermination shall be effective
2 as of the date of the individual's application for medical
3 assistance.

4 **SEC. 8. REIMBURSEMENT OF THIRD PARTIES FOR 2006**
5 **TRANSITION COSTS.**

6 (a) REIMBURSEMENT.—

7 (1) IN GENERAL.—Notwithstanding section
8 1935(d) of the Social Security Act (42 U.S.C.
9 1396u–5(d) or any other provision of law, the Sec-
10 retary of Health and Human Services shall reim-
11 burse covered third parties for 100 percent of the
12 costs incurred by the covered third party during
13 2006 for covered part D drugs for part D eligible in-
14 dividuals who are enrolled in a prescription drug
15 plan under part D of title XVIII of such Act (or an
16 MA–PD plan under part C of such title) which the
17 individual reasonably expected would have been cov-
18 ered under such part but were not because the indi-
19 vidual was unable to access on a timely basis pre-
20 scription drug benefits to which the individual was
21 entitled under such part. Such payments shall be
22 made from the Medicare Prescription Drug Account
23 under section 1860D–16 of the Social Security Act
24 (42 U.S.C. 1395w–116) and shall be deemed to be
25 payments from such Account under subsection (b) of



1 such section. The provisions of clauses (ii) through
2 (iv) of subparagraph (F) of paragraph (4) of section
3 1860D–4(b) of the Social Security Act, as added by
4 section 2(a), shall apply under this paragraph in the
5 same manner as they apply under such paragraph
6 (4).

7 (2) SANCTIONS FOR FRAUDULENT CLAIMS.—
8 The provisions of subclause (II) of section 1860D–
9 4(b)(4)(C)(i) of the Social Security Act, as added by
10 section 2(a), shall apply to a covered third party
11 with respect to a claim for reimbursement under
12 paragraph (1) in the same manner that such provi-
13 sions apply to a pharmacy in connection with a
14 claim for reimbursement under subclause (I) of such
15 section 1860D–4(b)(4)(C)(i).

16 (3) RETROACTIVE APPLICATION TO BEGINNING
17 OF 2006.—The costs incurred by a third party which
18 may be reimbursed under paragraph (1) shall in-
19 clude costs incurred during the period beginning on
20 January 1, 2006, and before the date of enactment
21 of this Act.

22 (b) RECOVERY OF COSTS FROM PLANS BY SEC-
23 RETARY.—The Secretary of Health and Human Services
24 shall establish a process for recovering the costs described
25 in subsection (a)(1) from prescription drug plans and



1 MA–PD plans if the Secretary determines that such plans
2 should have incurred such costs. Amounts recovered pur-
3 suant to the preceding sentence shall be deposited in the
4 Medicare Prescription Drug Account described in sub-
5 section (a)(1).

6 (c) DEFINITIONS.—For purposes of this section:

7 (1) COVERED PART D DRUG.—The term “cov-
8 ered part D drug” has the meaning given such term
9 under section 1860D–2(e) of the Social Security Act
10 (42 U.S.C. 1395w–102(e)).

11 (2) COVERED THIRD PARTY.—The term “cov-
12 ered third party” means any individual or party
13 (such as a State, charity, or family member of the
14 part D eligible individual involved) other than a
15 party that is obligated under part D of title XVIII
16 of the Social Security Act to incur the costs in-
17 volved. Such term shall not include a pharmaceutical
18 company or an assistance program sponsored or as-
19 sisted (in whole or in part) by such company.

20 (3) MA–PD PLAN.—The term “MA–PD plan”
21 has the meaning given such term under section
22 1860D–41(a)(14) of the Social Security Act (42
23 U.S.C. 1395w–151(a)(14)).

24 (4) PART D ELIGIBLE INDIVIDUAL.—The term
25 “part D eligible individual” has the meaning given



1 such term under section 1860D–1(a)(3)(A) of the
2 Social Security Act (42 U.S.C. 1394w–
3 101(a)(3)(A)).

4 (5) PRESCRIPTION DRUG PLAN.—The term
5 “prescription drug plan” has the meaning given
6 such term under section 1860D–1(a)(3)(C) of the
7 Social Security Act (42 U.S.C. 1394w–
8 101(a)(3)(C)).

9 (6) STATE.—The term “State” includes the
10 District of Columbia.

